REMARKS

Applicant expresses gratitude to the examiner for withdrawing the rejections of claims 28-42 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, the rejection of claims 30-31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, and the rejection of claims 32 and 33 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. By this amendment, claims 28 and 35-37 have been amended and claim 44 has been added. No new matter has been added.

Response to Rejections under 35 U.S.C. § 112

Claim 43 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the specification does not specifically teach a crosslinked polyacrylic acid. The Examiner asserts that the specific recitation of a carbopol in the specification is Carbopol 907 (page 7, line 1 of the specification), which the Examiner asserts is a linear polyacrylate. The Applicant respectfully disagrees. The Applicant submits that the same sentence in the specification also discloses Carbomer 934P which is a crosslinked polyacrylic acid. Moreover, the term 'carbopols' includes both linear and cross-linked polyacrylic acids, by definition. The Examiner is referred to, for example, U.S. Patent 6,245,351, which states that "[e]xamples of the polymers having an acidic dissociating group, and showing pH-dependent swelling include crosslinked acrylic polymers, such as Carbomer™ 934P, 940, 941, 974P, 980 and 1342, polycarbophil, calcium polycarbophil

(all produced by BF Goodrich Company)…" (col. 4, lines 48-52). *See also*, de Clercq and Luczak, "Antiviral Activity of Carbopol, a Cross-Linked Polycarboxylate," Archives of Virology, (1976), submitted on May 17, 2010. Thus, the Applicant submits that claim 43 complies with the written description requirement and respectfully requests that the rejection be withdrawn.

Claims 28-37, 39 and 41-43 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner asserts that it is not clear which substances would function as isotonicizing substances and that the specification does not provide a definition to define the metes and bounds of this term as used in the claims. The Applicant respectfully disagrees. The Applicant submits that the term 'isotonicizing substance' designates an auxiliary substance employed for adjusting the isotonicity of a solution to be used for injection or infusion. It is well-known to those of ordinary skill in the art that isotonicizing agents are, for example, salts and sugars that are added to pharmaceutical compositions to create physiological electrolyte concentrations in the compositions. For example, the Examiner is referred to the newly cited reference, Muller (U.S. 5,624,903), in which glycerol, glucose, mannitol, sodium chloride, calcium chloride, and magnesium chloride are mentioned as specific examples of isotonicizing substances. *See* col. 4, lines 9-11. Thus, because the presently claimed method involves application of a composition to vaginal tissue of a mother, one of ordinary skill in the art would know the metes and bounds of "isotonicizing substances" based on his or her knowledge of human physiology. Applicant respectfully requests that the rejection be withdrawn.

Claims 35 and 36 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner asserts that it is not clear in which application step the 5 to 200 mL or 10 to 100 mL of the composition is applied. Applicant submits that claims 35 and 36 have been amended to specify that the composition is applied in step 1. Written description support for this language can be found in the last paragraph of page 9. Applicant respectfully requests that the rejection be withdrawn.

Claim 37 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner asserts that claim 28, from which claim 37 depends, already recites multiple application steps, thus it is not clear if claim 37 is drawn to the already recited multiple application steps or additional multiple application steps. Applicant submits that claim37 has been amended to specify that the composition is applied in step 2. Written description support for this language can be found on page 9, third full paragraph. Applicant respectfully requests that the rejection be withdrawn.

Response to Rejections under 35 U.S.C. § 103

Claims 28, 30, 32-34, 37, 39, 41, and 42 were rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Müller (U.S. 5,624,903) and Bringloe (U.S. 4,765,478). The Examiner asserts that Kasahara discloses a composition comprising fucoidin and alginic acid that does not contain alkali metal phosphates and may be mixed with water, sodium polyacrylate, and carboxymethyl cellulose (CMC), and glucose (col. 5, lines 43-

45) for lubricating the birth canal to facilitate the delivery of the fetus (see col. 5, lines 16-42 of Kasahara). The Examiner asserts that glucose is an isotonicizing substance as evidenced by Muller (col. 4, lines 9-10 of Muller). The Examiner acknowledges that Kasahara does not mention humectants, but asserts that Van Leuven discloses humectants (1.2 o 2.5% propylene glycol and glycerol) in lubricant compositions. The Examiner further asserts that based on Kasahara's disclosure that the composition is a mucous, thready composition (col. 2, lines 7-8 of Kasahara), one skilled in the art would reasonably expect the composition to be in the form of a gel and that Bringloe discloses that CMC is a known gelling agent (col. 3, lines 46-53 of Bringloe). With regard to the application steps, the Examiner maintains that Kasahara discloses application of the composition "just before parturition" which the Examiner contends as including the time before labor or dilation begins, as well as the dilation phase and cites the definition of parturition from The American Heritage Stedman's Medical Dictionary which defines parturition as "[t]he process of labor and delivery in the birth of a child." The Examiner acknowledges that Kasahara is silent to multiple application steps, but asserts that it would be obvious because it is a design choice within the purview of the skilled artisan.

Applicant respectfully disagrees with the rejections for the following reasons:

<u>The prior art does not suggest the presently claimed method steps.</u>

Applicant submits that the combination of references does not suggest the presently claimed method. The presently claimed method requires at least two steps. The Examiner has acknowledged that Kasahara discloses application of the composition "just before parturition," but has not cited any suggestion in the cited references of a second method step of additionally applying an amount of the

composition to the birth canal surface during labor wherein the additional amount is effective in keeping the birth canal surface covered with the lubricant composition so that a lubricant layer is formed between the birth canal surface and the item to be delivered until the item is delivered. Thus, Applicant submits that independent claim 28 is distinguished over the combination of cited art for at least this reason.

With regard to the claim limitation that "a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered," the Examiner relies on the disclosure in Kasahara that states that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30) to assert that one would reasonably expect a lubricant layer to be formed between the birth canal surface and the item to be delivered.

Unexpected properties must always be considered in the determination of obviousness. "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher" *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus, the Applicant respectfully disagrees with this assertion because Kasahara's description of the composition as being thready and therefore "not likely to escape between the frictional interfaces" does not render method step 2 obvious. Kasahara merely describes the properties of the composition and not an active method step of applying additional amounts of the composition to maintain the lubricant layer that was formed in step 1 until the item to be delivered is delivered. The Examiner has not cited any

reference that suggests this step and the assertion that it is merely a design choice is unsubstantiated. None of the cited references suggest a method of maintaining a lubricant film layer or the step of re-applying the composition throughout labor until the items to be delivered are delivered. Thus, Applicant submits that it is improper for the Examiner to dismiss a required method step as merely a design choice within the purview of those skilled in the art.

The prior art does not suggest the composition for use in presently claimed method.

The disclosure of the applicant cannot be used to hunt through the prior art for the claimed elements and then combine them as claimed. *In re Laskowski*, 871 F.2d 115, 117, 10 USPQ2d 1397, 1398 (Fed. Cir. 1989). The composition of Kasahara is an aqueous solution, whereas the present claims are limited to a paste, gel, cream, suppository, or foam. Applicant submits that the Examiner's reliance on the mention of CMC in Kasahara in rejecting this distinguishing feature is based on improper hindsight. The mere fact that prior art may be modified to produce the claimed product does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 23 USPQ.2d 1780 (Fed. Cir. 1992); see, also, *In re Papesch*, 315, F.2d 381, 137 USPQ 43 (CCPA 1963). In addition, if the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *See In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Here, the composition for use in the claimed method has unexpected properties that cannot be realized if prepared in the form of an aqueous solution as in Kasahara. Kasahara's formulation is purported to have particular properties, e.g., being thready,

when prepared as an aqueous solution. Thus, if one were to modify Kasahara's solution in order to create a paste, gel, cream, suppository, or foam as required by the present claims, there is no expectation that the formulation would remain operable in the method of Kasahara. Thus, Applicant submits that independent claim 28 is distinguished over the combination of cited art for this reason as well.

The Kasahara composition is unsuitable for the use alleged by the Examiner.

Applicant has submitted photographs in a previous declaration showing compositions made according to Kasahara's formulation. The Examiner asserts that despite the dark color, the composition would be capable for use as a lubricant, absent evidence to the contrary. Applicant respectfully disagrees. Kasahara's formulation would not be useful for human vaginal birthing because the transparency of the lubricant is essential for it being used in human vaginal child birthing so as to allow visual inspection of the birth canal during labor. If the formulation of Kasahara is used, the practicioner will be impaired in his ability to supervise the birthing process.

Moreover, Kasahara's composition uses significant amounts of biological material, which render its production irreproducible and insufficiently sterile for an approved method human child birthing. Because the proteins in Kasahara's biological products would denature and precipitate as a result of a heat-sterilization process, it would no longer have the desired properties if one were to attempt to sterilize it. Thus, Applicant submits that it would not have been obvious to one of ordinary skill in the art to modify Kasahara in a way to arrive at the presently claimed method. In view of the art as a whole at the time of filing the application, one of ordinary skill in the art would

not have reasonably expected success in practicing the presently claimed method in humans.

There remains an unsatisfied and long-felt need for the presently claimed method.

The Examiner also considers the arguments regarding secondary considerations with respect to long-felt need and unmet need as not being convincing. The Examiner asserts that such long-felt and unmet need has been satisfied by Kasahara's composition. Applicant respectfully disagrees. The Examiner does not appear to dispute that there was a long-felt need for a method as presently claimed, but seems to assert that Kasahara's mention of treating women is evidence that the need was satisfied. The previously submitted declarations by third party practicioners as well as the inventor, who is a practicing obstetrician, avow that the method of Kasahara is not currently practiced **and that attempts to reproduce Kasahara's method have been unsuccessful**. Nevertheless, the Examiner requests evidence to the contrary. Applicant submits that is impossible to prove a negative, i.e., that Kasahara's method has not been used to satisfy the long-felt and unmet need. However, in the absence of any published clinical studies, follow-up research articles, patent applications that describe or actually claim Kasahara's purported birthing methods, or medical or news articles about the method subsequent to Kasahara's 1974 patent application, Applicant submits that the lack of evidence speaks for itself and supports the arguments for an unsatisfied long-felt need. If Kasahara had solved the need, there should be some record of the method in medical protocols or literature. Because such evidence does not exist, we disagree with the Examiner's summary dismissal of an unsatisfied need.

To provide further evidentiary support for Applicant's position that there was a long-felt and unmet need, Applicant encloses herewith the complete collection of practice papers published after the filing date by Lamaze International entitled "Care Practices that Promote Normal Birth" in the Journal of Perinatal Education, Vol. 13, No. 2, (2004) pages 1-41. These papers demonstrate that the contemporaneously accepted practices for human child birthing do not include any suggestion of the method as presently claimed, or the method of Kasahara that the Examiner contends has solved the unmet need for safer, more natural, and lower friction births. Indeed, there is no mention of any lubricant use at all, but the scope of the long-felt and unmet need is described as follows:

> Over 60% of the American women in the survey received epidural anesthesia during labor, and almost 10% of the vaginal births were instrument deliveries. More than 90% of the surveyed women had electronic fetal monitoring (EFM) rather than intermittent auscultation, although the routine use of EFM increases the cesarean rate with no change in infant mortality or morbidity (Thacker, Stroup, & Chang, 2003; Enkin, et al., 2000). Page 2, left col., 2nd full paragraph.

The above statistics are described as being "alarming" and that there is increased risk as a result of such medical births, which are increasingly prevalent. Also enclosed is a 2010 article entitled "Worldwide cesarean section rates at 'epidemic proportions', docs warn C-sections aren't always safer," which states that:

> U.S. studies have shown babies born by cesarean have a greater chance for respiratory problems. The Asia survey found the procedure benefits babies during breech births.
>
> Reasons for elective C-sections vary globally, but increasing rates in many developing countries coincide with a rise in patients' wealth and improved medical facilities.
>
> In Asia, some women opt for the surgery to choose their delivery day after consulting fortune tellers for "lucky" birthdays or times. Others fear painful

> natural births or worry their vaginas may be stretched or damaged by a normal delivery. Some women also prefer the operation because they mistakenly believe it is less risky.

This oft-cited 'cesarean epidemic' is proof of the unsatisfied need for a safer and lower friction vaginal childbirth method. As physicians and patients are still confronted with the complications of the vaginal route, the cesarean method has become much more prevalent as a response to these complications. However, the present method provides a safer and more desirable alternative to unnecessary surgery. Enclosed is a market research survey performed by GfK in Central Europe with approximately 600 patients and 400 physicians. The results of the survey show that women and physicians consider there to be a need for such a product, thereby demonstrating an unsatisfied need.

<u>The presently claimed method has unexpected and surprising advantages in view of recommended modern birthing techniques.</u>

Applicant refers to the Lamaze Care Practice Papers, specifically practice numbers 2 and 5. Practice Paper Number 2 discloses the benefits of mother's being free to move throughout labor. The paper discloses that "a laboring woman's lower back pain is significantly worse in active labor when she is in a supine (lying-down) position." (page 12, right column, 1st full paragraph). The Paper states that "[b]irth is an active process" and that the laboring woman should be allowed to move without restrictions. Kasahara discloses the use of an aqueous solution, which would not be useful in a supine-position birth. The presently claimed method uses a composition with surprising bioadhesive properties. These properties provide the unexpected advantage of allowing the laboring woman to be ambulatory with the lubricant in place during labor.

Further, the lubricant is re-applied according to the presently claimed method to keep the birth canal surface covered so that a lubricant layer is formed between the surface and the item to be delivered until the item is delivered, even while the mother is free to move around according to the recommendations of Lamaze International. Accordingly, Applicant submits that the presently claimed method provides unexpected advantages that were not suggested by any combination of the cited art.

Applicant further refers to Care Practice Paper Number 5, which discloses the advantages of non-supine positions for birth. The abstract of the article discloses that non-supine position births "facilitate rotation and descent of the baby and result in reduced duration of second state, a reduction in episiotomies, and fewer abnormal fetal heart rate patterns." The surprising bioadhesive properties of the composition for use in the presently claimed method allows the lubricant to stay in place in a mother giving birth in any position, including non-supine positions. Accordingly, the laboring woman has unexpected flexibility in range of movement and birthing positions. Accordingly, Applicant submits that the presently claimed method provides unexpected advantages that were not suggested by any combination of the cited art.

The presently claimed method is intended to ease child birthing as a proactive step, which is intended to be initiated with the onset of labor and additionally applied to keep the birth canal surface covered so that a lubricant layer is formed between the surface and the item to be delivered until the item is delivered. Aqueous solutions, such as those used in the veterinary arts and in Kasahara, would not be applicable in humans because 1) they would be expelled by the mother's movement and/or during water births, and also by the progression of item to be delivered through the birth canal,

and 2) a practitioner cannot safely or practically continuously pump an aqueous lubricant into a human mother as is the procedure in animals. The presently claimed method avoids these disadvantages by using the presently claimed composition which has superior bioadhesive properties, allowing the mother to be ambulatory during labor, is suitable for water births, is not an aqueous solution and does not require a practitioner to apply large amounts.

Indeed, the presently claimed method is the only lubricant birthing composition and method that has been approved for, and is presently being used for, human birthing in Europe and South America. Thus, this is clear objective evidence that there was previously no recognized and approved method and now there is a recognized and approved method for human birthing facilitation. By definition, the present inventor has recognized a long-felt and unmet need in his field of medical practice, looked to the state of the art for a solution, and, finding that there was no workable solution, invented a new and useful composition and method that has been commercially successful worldwide.

<u>The presently claimed method and composition are supported by clinical trial data and regulatory approval.</u>

The previously submitted paper (Schaub, 2008, J. Perinat. Med.) provides clinical trial data showing a significant reduction in second stage labor time and perineal tears by using the presently claimed method. Thus, it is clear that there is an need, i.e., reduction in perineal tears and labor time, satisfied by the presently claimed method.

Thus, Applicant submits that sufficient secondary considerations demonstrate that the presently claimed method is non-obvious.

Applicant refers to the previously submitted declaration of the inventor, Dr. Andreas Schaub. In 2004, Dr. Schaub commissioned a pharmacist, Dr. B. Kreyenbühl, to reproduce the formulation of Kasahara for use in human birthing. In his declaration, Dr. Schaub provides the communications and test reports of Dr. Kreyenbühl and provides a summary translation thereof. Dr. Kreyenbühl notes that the exact ingredients of Kasahara were not commercially available because Kasahara teaches that they were obtained from seaweed belonging to the class of brown algae collected in the waters around Japan. As is generally accepted by a person skilled in the art of marine chemistry, both the nature and the amount of the chemical compounds in a specific marine organism differs depending on the habitat of the organism, i.e., the collection site, and the collecting season due to environmental influences. Nevertheless, Dr. Kreyenbühl obtained the closest available substitute, namely sodium alginate and fucoidin to be used in preparation of the composition described in Kasahara. Dr. Kreyenbühl prepared the formulation and found it to be a viscous, dark brown paste/gel with very limited shelf-life. The resulting gel was manually tested for lubrication potential and bioadhesivity because Dr. Schaub intended to test the composition for use in human birthing. However, the composition of Kasahara did not have the necessary properties required for human birthing in terms of lubrication, appearance, reproducibility, standard guideline for production, sterility, commercial applicability, or shelf-life. As a result, Dr. Schaub was not able to use the composition based on the disclosure in Kasahara. Accordingly, quantitative comparison is impossible and futile

because no scientifically credible test can compare a composition that is not suitable for the intended purpose. The presently claimed method has undergone clinical trials and is approved by medical regulatory agencies in many countries. In contrast, the methods cited from the prior art are not approved and there is no evidence of any clinical trials.

In view of the above, Applicant submits that it is highly unlikely that any medical oversight board would authorize a clinical study involving the composition of Kasahara for human child birthing. Therefore, Applicant respectfully submits that the unmet need has clearly not been satisfied by Kasahara as the Examiner contends.

Applicant submits that no combination of the cited references suggests the presently claimed method steps. One of ordinary skill in the art at the time of the invention would have been an obstetrician. Because there was no analogous approved method for human use, an obstetrician would have lacked any training to be able to obviously arrive at the presently claimed method steps. As such, Applicant submits that it would not have been obvious to one of ordinary skill to practice the presently claimed method in any way other than those known in the veterinary field. An obstetrician reading Kasahara would have been unable to produce a medically useful composition based on Kasahara's teaching for the reasons detailed above. Thus, based on the above amendments and arguments, Applicant submits that the presently claimed method is not rendered obvious by the combination of the cited art and respectfully requests that the rejection of claim 28 be withdrawn. Claims 30, 32-34, 37, 39, and 41-42, which depend from claim 28 should be allowable for at least the above reasons. Applicant respectfully requests that the rejections be withdrawn.

Claim 29 was rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller (U.S. 5,624,903) and Bringloe (U.S. 4,765,478) and further in view of JP 46-24256 ("JP '256"). The Examiner acknowledges that Kasahara, Van Leuven and Bringloe are silent as to the amount of sodium polyacrylate, but asserts that JP '256 discloses that sodium polyacrylate is a useful lubricant during birth and that the lubricant does not lose activity when diluted to 0.2-0.3% concentration. Thus, the Examiner asserts that one of ordinary skill would have been motivated to manipulate the amount of sodium polyacrylate to optimize lubricity. Applicant maintains that the JP '256 demonstrates the difference between the veterinary and human applications of birthing methods. Such veterinary references do not teach toward the presently claimed method, but rather, they teach the use of aqueous solutions, prepared by dilution in water, and application to the animal's vagina at the time of birth. Moreover, none of the methods in the cited references disclose the step of applying additional amounts of the composition to keep the birth canal surface covered so that a lubricant layer is formed between the surface and the item to be delivered until the item is delivered. Thus, based on the above amendments and arguments, Applicant submits that the presently claimed method is not rendered obvious by the combination of the cited art and respectfully requests that the rejection of claim 29 be withdrawn. Further, Applicant submits that claim 29 depends from claim 28, which is not rendered obvious by the combination of Kasahara and Van Leuven in view of Muller and Bringloe and that JP '256 does not cure the deficiencies of the combination. Thus, Applicant submits that claim 29 is not rendered

obvious by any combination of the cited art and respectfully requests that the rejection be withdrawn.

Claim 31 was rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller (U.S. 5,624,903) and Bringloe (U.S. 4,765,478) and further in view of Behl et al. (U.S. 5,580,574). The Examiner asserts that Behl discloses pharmaceutical compositions having CMC in the range of 2 to 5%. Behl is directed to making pharmaceutical compositions for transdermal delivery. The Applicant maintains that one very important feature of the present invention is that the composition is formulated in such a manner as to largely avoid transdermal penetration, which would be dangerous and not suitable. Absorption would lead to a diminishing lubricity over labor time and pose a danger to the mother. The Applicant submits that one of ordinary skill intending to produce a suitable birthing gel would not look to a reference for producing transdermal pharmaceutical delivery compositions. The disclosure of the applicant cannot be used to hunt through the prior art for the claimed elements and then combine them as claimed. *In re Laskowski*, 871 F.2d 115, 117, 10 USPQ2d 1397, 1398 (Fed. Cir. 1989). The Applicant submits that the presently claimed method is not rendered obvious by the combination of the cited art and respectfully requests that the rejection of claim 31 be withdrawn. Further, Applicant submits that claim 31 depends from claim 28, which is not rendered obvious by the combination of Kasahara and Van Leuven in view of Muller and Bringloe and that Behl does not cure the deficiencies of the combination. Thus,

Applicant submits that claim 31 is not rendered obvious by any combination of the cited art. Applicant respectfully requests that the rejection be withdrawn.

Claims 35-36 were rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller (U.S. 5,624,903) Bringloe (U.S. 4,765,478) and further in view of Kasahara '797 (U.S. Patent 3,814,797). The Examiner asserts that no new arguments were provided, thus these claims remain obvious because of the maintained rejection of independent claim 28. Applicant submits that claims 35 and 36 have been amended to recite that the specifically recited amounts of the composition are applied to the surface of the birth canal in step 1. Applicant submits that no combination of the cited references suggests the method steps recited in independent claim 28 and thus, no combination of the cited art can render claims 35 and 36 obvious. Applicant respectfully requests that the rejection be withdrawn.

Claim 43 wasrejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Dettmar (U.S. Patent 4,652,446). The Examiner asserts that Kasahara discloses sodium polyacrylate and that Dettmar denotes that sodium polyacrylate may be linear or cross-linked (col. 1, line 44-46). Thus, the Examiner asserts that it would have been obvious to use cross-linked polyacrylic acid. Applicant submits that no combination of the cited references suggests the method steps recited in independent claim 28 and thus, no combination of the cited art can render claims 35 and 36 obvious. Applicant respectfully requests that the rejection be withdrawn.

New Claim

Independent claim 44 has been added to define further embodiments of the invention. Written description support for this claim can be found on page 4, lines 4-24, the paragraph bridging pages 5 and 6, and pages 5-7. No new matter has been added. Applicant submits that the presently claimed method steps alone differentiate the claims from the combination of the cite art. However, claim 44 further limits the claimed method by limiting the lubricant film-forming combination using "consisting of" language. Accordingly, the method recited in claim 44 is further distinguished from the combination of the cited art because the composition of Kasahara requires fucoidin and alginic acid salt as the essential lubricant film-forming ingredients and Van Leuven does not disclose polyacrylic acids at all. Applicant respectfully requests that claim 44 be entered and indicated allowable.

Conclusion

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

A Notice of Allowance is respectfully requested.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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RBM/AHH
Enclosures: 1) Care Practices Positions Papers, pages 1-41
2) NY Daily News Article dated January 13, 2010
3) GfK doctor and patient survey results

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